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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/490,643 01/24/00 MINSHULL

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EXAMINER

WHISENANT, E

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/490,643

Applicant(s)
Minshull et al.

Examiner
Ethan Whisenant, Ph.D. (FSA)

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 MAY 01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-104, 106-148, and 150-152 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-104, 106-148, and 150-152 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 20) ☐ Other: _____

DETAILED ACTION

1. The applicant's request for a RCE has been entered. The applicant's request was received on 16 MAY 01 and has been entered as paper no. 12. The claims pending in this application are **Claims 31-104, 106-148 and 150-152**. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

3. Claim(s) 31-104, 106-148 and 150-152 is/are rejected under 35 U.S.C. 102(e) as anticipated by Jerrell [US Patent No. 5,498,531 (1994)].

Jerrell teach a method for combinatorial cassette-based recombination which comprises all of the limitations recited in Claims 31 and 33. Note that Jarrell teach conjoining a plurality of recombination sites to a plurality of subsequences of at least one nucleic acid to thereby produce a

plurality of recombination cassettes". See, for example, Column 30 beginning at about line 6. Note also the definition of "cassette mutagenesis" recited by Short in Column 8, beginning at about line 29 of US Patent No. 5,939,250.

35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102/103

6. Claim(s) 31-104, 106-148 and 150-152 is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stemmer [Nature 370 : 389-391 (1994)].

Stemmer teaches a method for combinatorial cassette-based recombination which comprises all of the limitations recited in Claims 31 and 33. Admittedly, however, Stemmer does not explicitly use the phrase "conjoining a plurality of recombination sites to a plurality of subsequences of at least one nucleic acid to thereby produce a plurality of recombination cassettes", to describe his invention. However, this is exactly what is occurring during the early steps/cycles of the method described by

Stemmer. Therefore absent a showing to the contrary, this limitation is considered to be inherent to the method described by Stemmer.

7. Claim(s) 31-104, 106-148 and 150-152 is/are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cremari et al. [Nature Biotechnology 14 : 315-319 (MAR 1996)].

Cremari et al. teach a method for combinatorial cassette-based recombination which comprises all of the limitations recited in Claims 31 and 33. Admittedly, however, Cremari et al do not explicitly use the phrase "conjoining a plurality of recombination sites to a plurality of subsequences of at least one nucleic acid to thereby produce a plurality of recombination cassettes", to describe their method. However, this is exactly what is occurring during the early steps/cycles of the method described by Cremari et al. Therefore absent a showing to the contrary, this limitation is considered to be inherent to the method described by Cremari et al.

DOUBLE PATENTING

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim(s) 31-104, 106-148 and 150-152 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-36 of U.S. Patent No. 5,837,485. Although the conflicting claims are not identical, they are not patentably distinct. It is noted that Minshull et al. in their claims in US Patent No. 5,837,485 do not explicitly use the phrase "conjoining a plurality of recombination sites to a plurality of subsequences of at least one nucleic acid to thereby produce a plurality of recombination cassettes", however this is exactly what is occurring during the early steps/cycles of, for example, Claims 1-3 of U.S. Patent No. 5,837,485. The scope encompassed by Claims 31-152 of the instant application falls within the broad scope encompassed by Claims 1-36, therefore the granting of a patent on Claims 31-152 of the instant application would improperly extend the "right to exclude" previously granted in U.S. Patent No. 5,837,485.

RESPONSE TO APPLICANT'S AMENDMENT/ ARGUMENTS

10. Applicant's arguments with respect to the claimed invention have been fully and carefully considered but are not considered to be persuasive. The applicant should, in their next response, explain what limitation(s) present in the claims distinguishes the claimed invention over the prior art.

CONCLUSION

11. Claim(s) 31-104, 106-148 and 150-152 is/are rejected and/or objected to for the reason(s) set forth above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, PhD. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST. If attempts to reach the examiner by

Serial Number: 09/490,643
Art Unit: 1655

6

telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Art Unit is (703) 308-8724. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in dark ink, appearing to read 'EWH' followed by a stylized flourish.

Ethan Whisenant, Ph.D.
Primary Examiner (FSA)